IN THE CLAIMS

Please consider the following previously presented claims 26, 28-29, 32 - 34, 38, 39, 41, 43, 46- 47, 52 and 54, and new claims 55-68.

Please cancel claims 17-25, 27, 31, 35, 37, 40, 42, 44, 45, 48-51 and 53.

The status of the claims and amendments to the claims, if any, are outlined in the attached APPENDIX.

attached AFFENDIA.
26. (Previously Amended) A glassy state composition which is storage-stable at 20° C,
comprising:
(1) a carrier substance which is water-soluble or water-swellable and
(2) at least one material to be stored which is dissolved in said amorphous carrier
substance;
wherein said at least one material comprises a purified biologically active material
that is unstable in aqueous solution at 20° C;
wherein said purified biologically active material is selected from the group consisting
of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or
nucleotides, enzyme cofactors and derivatives of any of the foregoing, said derivatives having
one or more additional moieties bound thereto;
wherein said composition has the properties that it is storage stable and exists in a
glassy state when at 20° C;
wherein a weight ratio of said purified biologically active material to said carrier
substance is between about 2:1 and about 1:1; and
wherein said biologically active material is not an enzyme.
28. (Previously Amended) The composition of claim 46 wherein said ratio is about 2:1.
29. (Previously Amended) The composition of claim 46 wherein said ratio is about 1:1.
32. (Previously Amended) A method of rendering a material storage stable at 20° C which
material is unstable in aqueous solution at room temperature of 20° C, comprising the steps
<u>of:</u>
(1) dissolving to form an aqueous solution
(a) said material and
(b) a carrier substance which is water-soluble or water-swellable;

TORNEY CLIENT AND WORK PRODUCT PRIVILEGED DOCUMENT (2) evaporating liquid water from said solution thereby converting said solution into a glassy state composition; wherein said material comprises a purified biologically active material that is unstable in aqueous solution at 20° C; wherein said biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto; wherein said composition has the property that it is storage stable and exists in said glassy state when at 20° C; and wherein a weight ratio of said purified biologically active material to said carrier substance is between about 1:2 and about 1:1; and wherein said biologically active material is not an enzyme. 33. (Previously Amended) The method of claim 47 wherein said weight ratio is about 1:1. 34. (Previously Amended) The method of claim 47 wherein said weight ratio is about 1:2. 38. (Amended) A method of forming a composition which is storage-stable at 20° C, said composition comprising: (1) dissolving to form an aqueous solution (a) a carrier substance which is water-soluble or water-swellable and (b) at least one material to be stored; (2) forming said solution containing said carrier substance with said at least one material dissolved therein into a glassy state by evaporation of liquid water to produce said composition; wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution at 20° C;

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wherein said composition contains no more than 4 percent by weight of water; and

of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or

nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said

derivatives having one or more additional moieties bound thereto; and

wherein said purified biologically active material is selected from the group consisting

ATTORNEY CLIENT AND WORK PRODUCT PRIVILEGED DOCUMENT wherein said composition has the properties that it is storage stable and exists in a glassy state when at 20° C; and wherein said step of dissolving comprises dissolving in an aqueous solution having a pH of about 7; with proviso that when said at least one material comprises an enzyme, said enzyme comprises an enzyme selected from dehydrogenase enzymes, restriction enzymes, oxidase enzymes, and reductase enzymes. A composition which is storage-stable at 20° C, comprising: 39. (1) a carrier substance which is water-soluble or water-swellable and is in a glassy state; (2) at least one material to be stored which is dissolved in said carrier substance; wherein said composition exists in a glassy state at 20° C; wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution at 20° C; wherein said purified biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto; wherein said composition contains no more than 4 percent by weight of water; and wherein said biologically active material is not rennin. 41. A composition which is storage-stable at 20° C, comprising: (1) a carrier substance which is water-soluble or water-swellable and (2) at least one material to be stored which is dissolved in said carrier substance; wherein said composition has the property that it exists in a glassy state when at 20° <u>C;</u> wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution at 20° C; wherein said biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said

derivatives havin	g one or mo	ore additional moieties bound thereto;	
wherein s	aid compos	sition contains no more than 4 percent by weight of water; and	
wherein s	aid biologic	cally active material is not rennin.	
43. (Previously A	mended)	A composition which is storage-stable at 20° C, comprising:	
(1) a carri	er substanc	ce which is water-soluble or water-swellable and	
(2) at leas	t one mater	rial to be stored which is dissolved in said carrier substance;	
wherein s	aid compos	sition has the property that it exists in a glassy state when at 20°	
<u>C;</u>			
wherein s	aid at least	t one material comprises a purified biologically active material	
that is unstable in	ı aqueous so	solution at 20° C;	
wherein s	aid biologic	ically active material is selected from the group consisting of	
peptides, proteins	s, nucleosid	des, nucleotides, dimers or oligomers of nucleosides or	
nucleotides, enzy	me cofacto	ors and derivatives of any of the foregoing, said derivatives havin	g
one or more addi	tional moie	eties bound thereto; and	
wherein s	aid biologic	ically active material is not an enzyme and is not freeze stable.	
46. (Amended)	A glas	assy state composition which is storage-stable at 20° C,	
comprising:			
(1) a carr	er substanc	ce which is water-soluble or water-swellable and	
(2) at least	st one mater	erial to be stored which is dissolved in said amorphous carrier	
substance;			
wherein s	aid at least	t one material comprises a purified biologically active material	
that is unstable in	1 aqueous s	solution at 20° C;	
wherein s	said purified	ed biologically active material is selected from the group consisting	18
of peptides, prote	eins, nucleo	osides, nucleotides, dimers or oligomers of nucleosides or	
nucleotides, enzy	mes, enzyr	me cofactors and derivatives of any of the foregoing, said	
derivatives havir	ig one or m	nore additional moieties bound thereto;	
wherein s			
<u> </u>	said compos	osition has the properties that it is storage stable and exists in a	
glassy state when			
glassy state when	n at 20° C;		

ATTORNEY CLIENT AND WORK PRODUCT PRIVILEGED DOCUMENT with proviso that when said at least one material comprises an enzyme, said enzyme comprises an enzyme selected from restriction enzymes, dehydrogenase enzymes, oxidase enzymes, and reductase enzymes. 47. A method of rendering a material storage stable at 20° C which material is unstable in aqueous solution at room temperature of 20° C, comprising the steps of: (1) dissolving to form an aqueous solution (a) said material and (b) a carrier substance which is water-soluble or water-swellable; (2) evaporating liquid water from said solution thereby converting said solution into a glassy state composition; wherein said material comprises a purified biologically active material that is unstable in aqueous solution at 20° C; wherein said biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto; wherein said composition has the property that it is storage stable and exists in said glassy state when at 20° C; and wherein a weight ratio of said purified biologically active material to said carrier substance is between about 1:2 and about 1:1; with proviso that when said at least one material comprises an enzyme, said enzyme comprises an enzyme selected from restriction enzymes, oxidase enzymes, and reductase enzymes. A composition which is storage-stable at 20° C, comprising: 52. (1) a carrier substance which is water-soluble or water-swellable and

(2) at least one material to be stored which is dissolved in said carrier substance;

<u>C:</u>

that is unstable in aqueous solution at 20° C;

wherein said composition has the property that it exists in a glassy state when at 20°

wherein said at least one material comprises a purified biologically active material

ATTORNEY CLIENT AND WORK PRODUCT PRIVILEGED DOCUMENT wherein said biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto; and wherein said biologically active material is not freeze stable; and with proviso that when said at least one material comprises an enzyme, said enzyme comprises an enzyme selected from dehydrogenase enzymes, restriction enzymes, oxidase enzymes, and reductase enzymes. A method of forming a composition which is storage-stable at 20° C, said composition comprising: (1) dissolving to form an aqueous solution (a) a carrier substance which is water-soluble or water-swellable and (b) at least one material to be stored; (2) forming said solution containing said carrier substance with said at least one material dissolved therein into a glassy state by evaporation of liquid water to produce said composition; wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution at 20° C; wherein said purified biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto; and wherein said composition contains no more than 4 percent by weight of water; and wherein said composition has the properties that it is storage stable and exists in a glassy state when at 20° C; and wherein said step of dissolving comprises dissolving in an aqueous neutral or slightly basic solution having a pH of about 7.

Please add the following new claims 55-68.

55. (New) A method of rendering a purified biologically active material storage-stable at
20° C and pharmacologically using said material, which material is unstable in aqueous
solution at 20° C, comprising the steps of:
(1) dissolving to form an aqueous solution of
(a) a purified biologically active material (i) which is unstable in aqueous
solution at 20° C and which is selected from the group consisting of peptides, proteins,
nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzyme cofactors
and derivatives of any of the foregoing, said derivatives having one or more additional
moieties bound thereto and (ii) which is not an enzyme and
(b) a carrier substance that is water-soluble or water-swellable;
(2) forming said solution into a glassy state composition by evaporating liquid water,
wherein said glassy state composition exists when at 20° C; and
(3) administering said purified biologically active material stored in said glassy state
composition.
56. (New) The method of claim 55 wherein said purified biologically active material is
selected from the group consisting of immunoglobulin, an enzyme cofactor, a nucleoside, a
nucleotide, a dinucleotide, a dimer of a nucleoside, a dimer of a nucleotide, an oligomer of a
nucleoside, and an oligomer of a nucleotide.
57. (New) The method of claim 55 wherein said purified biologically active material is
selected from the group consisting of a hormone, a transport protein, a blood clotting factor,
enzyme cofactor, a pharmacologically active protein, a transport protein, and a blood clotting
factor.
58. (New) The method of claim 55 wherein said purified biologically active material is a
hormone.
59. (New) The method of claim 55 wherein said purified biologically active material is an
immunoglobulin.
60. (New) The method of claim 55 wherein said purified biologically active material is a
blood clotting factor.
61. (New) The method of claim 55 wherein said purified biologically active material is a

pharmacologically active protein.
62. (New) The method of claim 55 further comprising the step of shaping said glassy
state composition.
63. (New) The method of claim 62 wherein said step of shaping comprises compressing
said glassy state composition into a tablet.
64. (New) A method of rendering a purified biologically active material storage-stable at
20° C, which material is unstable in aqueous solution at 20° C, comprising the steps of:
(1) dissolving to form an aqueous solution of
(a) a purified biologically active material, which is unstable in aqueous
solution at 20° C and which is selected from the group consisting of peptides, proteins,
nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes,
enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more
additional moieties bound thereto and
(b) a carrier substance that is water-soluble or water-swellable;
(2) evaporating liquid water from said solution, thereby converting said solution to a
glassy state composition, wherein said glassy state composition exists when at 20° C;
wherein said evaporating is done without heating; and
wherein said purified biologically active material is selected from the group consisting
of immunoglobulin, an enzyme cofactor, a nucleoside, a nucleotide, a dinucleotide, a dimer of
a nucleoside, a dimer of a nucleotide, an oligomer of a nucleoside, and an oligomer of a
nucleotide.
65. (New) A method of rendering a purified biologically active material storage-stable at
20° C, which material is unstable in aqueous solution at 20° C, comprising the steps of:
(1) dissolving to form an aqueous solution of
(a) a purified biologically active material which is unstable in aqueous solution
at 20° C and which is selected from the group consisting of peptides, proteins, nucleosides,
nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors
and derivatives of any of the foregoing, said derivatives having one or more additional
moieties bound thereto and
(b) a carrier substance that is water-soluble or water-swellable;

(2) evaporating liquid water from said solution thereby converting said solution into a
glassy state composition, wherein said glassy state composition exists when at 20° C;
wherein said evaporating is done without heating; and
wherein said purified biologically active material is selected from the group consisting
of a hormone, immunoglobulin, a transport protein, a blood clotting factor, a
pharmacologically active protein, a dehydrogenase, restriction enzyme, an oxidase enzyme, a
reductase enzyme, a transport protein, and a blood clotting factor.
66. (New) A method of rendering a purified biologically active material storage-stable at
20° C, which material is unstable in aqueous solution at 20° C, comprising the steps of:
(1) dissolving to form an aqueous solution of
(a) a purified biologically active material which is unstable in aqueous solution
at 20° C and which is selected from the group consisting of peptides, proteins, nucleosides,
nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors
and derivatives of any of the foregoing, said derivatives having one or more additional
moieties bound thereto and
(b) a carrier substance that is water-soluble or water-swellable;
(2) evaporating liquid water from said solution, thereby converting said solution into a
glassy state composition, wherein said glassy state composition exists when at 20° C;
wherein said evaporating is done without heating; and
wherein said carrier substance comprises a member of the group consisting of a
polysaccharide, a disaccharide, and a sugar that has a Tg of at least 55° C and not greater than
<u>150° C.</u>
67. (New) A glassy state composition which is storage-stable at 20° C, comprising:
(1) a carrier substance which is water-soluble or water-swellable;
(2) at least one material to be stored which is dissolved in said carrier substance;
wherein said glassy state composition including said carrier substance has the property
of being in a glassy state and being storage stable when at 20° C;
wherein said at least one material comprises a purified biologically active material
that is unstable in aqueous solution when at 20° C and is selected from the group consisting
of immunoglobulin, an enzyme cofactor, a nucleoside, a nucleotide, a dinucleotide, a dimer of

a nucleoside, a dimer of a nucleotide, an oligomer of a nucleoside, and an oligomer of a
nucleotide.
68. (New) A method of forming a glassy state composition which is storage-stable at 20°
C, comprising the steps of:
(1) dissolving to form an aqueous solution of (a) at least one material to be stored and
(b) a carrier substance which is water-soluble or water-swellable;
(2) evaporating water from said solution, thereby forming said glassy state
composition;
wherein said glassy state composition including said carrier substance has the property
of being in said glassy state and being storage stable when at 20° C;
wherein said at least one material comprises a purified biologically active material
that is unstable in aqueous solution when at 20° C and is selected from the group consisting
of immunoglobulin, an enzyme cofactor, a nucleoside, a nucleotide, a dinucleotide, a dimer of
a nucleoside, a dimer of a nucleotide, an oligomer of a nucleoside, and an oligomer of a
nucleotide.